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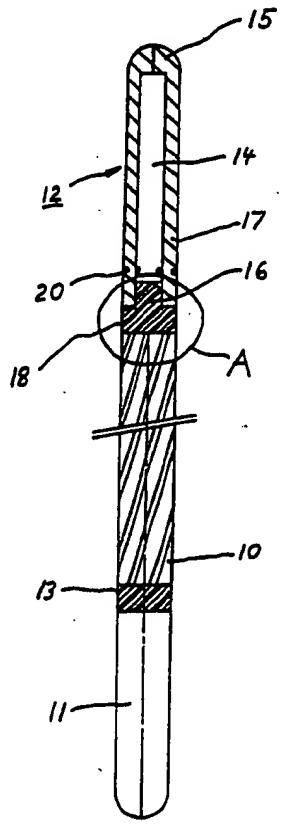
(54) Title: DEVICE FOR INTRODUCING A RADIOACTIVE SOURCE INTO THE BODY

(57) Abstract

The invention relates to a device for introducing a source of radioactive radiation into the body for therapeutic applications, comprising a flexible cable (10) to be introduced into the body through a catheter and a capsule (12), for sealingly containing the source (14) of radioactive radiation. The capsule (12) comprises a thin-walled (17) tubular reservoir having an open end which is sealingly connected to the flexible cable (10) so that the capsule is coaxial to the flexible cable and having closed end (15) with a rounded-off external shape. The capsule accommodates a quantity of iridium-192 (14) of a capacity sufficient for therapeutic application. The radioactive source (14) of iridium-192 is provided within the capsule (12) in the form of a single bar.



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DEVICE FOR INTRODUCING A RADIOACTIVE SOURCE INTO THE BODY

The invention relates to a device for introducing a source of radioactive radiation into the body for therapeutic application.

Such a device is known from United States Patent 3,750,653. This Patent discloses a thin-walled, narrow tube which is closed at its front end and which can be introduced into the human body, in particular into the uterus. The rear end portion stays outside the body, so that after positioning the tube, a source of radioactive material can be introduced into the tube. In certain embodiments the radioactive source is positioned in the tube by means of a rod-shaped element ("preformed elongated member") in the front portion of which the radioactive material is accommodated. In other embodiments shown in the patent the radioactive material is enclosed in a short plastic sheath which in some way reaches through the thin-walled tube to the closed front end portion.

One disadvantage of the embodiments utilizing a plastic sheath is that it is difficult to accurately position the source with radioactive material because the source cannot readily be handled. Moreover, the radiation cannot simply be terminated at will by removing the source of radiation. The source of radiation can be removed only together with the thin-walled tube, which actually restricts the application to radiation therapy in those body cavities where such a thin-walled tube can be introduced and removed without much discomfort. This considerably restricts the general applicability, because many tumors which are to be considered for a radiotherapeutic treatment are not present in or in the immediate proximity of such body cavities. Finally, plastics are generally unfit for accommodating a source of

radioactive radiation for therapeutic application, because plastics are not resistant to the high doses, e.g. in the order of several Curie, of radiation required for the therapeutic application, and therefore radioactive material may be released. General applicability is also restricted in the embodiments utilizing a rod-shaped element as described in the United States Patent 3,750,653, because many places in the body, notably the bronchi, are not accessible for such an element. This means that, although the radioactive source can be better positioned with respect to the tumor to be treated, many tumors cannot be treated radiotherapeutically by means of such a device. The use of catheterization has expanded enormously in medicine and allows for the almost unlimited possibilities of penetrating deeply into the body of a patient. However, such possibilities are seriously restricted by the use of a rod-shaped element as described in the above-mentioned United Stated Patent. In particular, many places which can be reached by a catheter, for example, various internal organs, cannot be reached with the radioactive source in a rod-shaped element.

United States patent 4,861,520 overcomes several of the problems noted above, and provides a device for introducing a source of radioactive radiation into the body for therapeutic application which satisfies the following conditions:

(i) it is possible to position the source of radiation accurately with respect to the tumor to be treated;

(ii) the source of radiation is safely enclosed in a metal capsule which is resistant to the radioactive radiation; and

(iii) the device is generally applicable, i.e. is also usable in the radiotherapeutic treatment of those

tumors which are difficult to access, in particular, lung tumors and tumors in those internal organs which are accessible by catheterization through the bloodstream or percutaneously.

The device described in U.S. patent 4,861,520 comprises a flexible cable which can be introduced into the body through a catheter and a capsule connected coaxially to the front end of the cable, the capsule sealingly accommodating a quantity of iridium-192 or a capacity sufficient for therapeutic application. The capsule comprises a thin-walled tubular reservoir with one end sealingly connected to the flexible cable and a second end being closed and having a rounded-off external shape.

The cable which must be flexible enough to follow the track of the catheter, is manufactured from a mechanically strong and radiation-resistant material, preferably from stainless steel. In order to achieve the desired flexibility the cable is composed of a bundle of twisted steel wires. At the end of the cable remote from the capsule, a solid end portion on which information regarding the nature of the radiation source, is provided. The capsule consists of a metal reservoir, preferably made of stainless steel, which is resistant to high doses of radioactive radiation. The one end of the reservoir is sealingly closed by a plug, the plug being connected to the flexible cable by welding. The cable and capsule are proportioned so that they can be maneuvered to the desired position through a catheter already provided in the body. This is of great importance because almost any place in the body is accessible for a catheter; such as body cavities, and other places in the body. The flexibility of the cable enables the radiation source to reach places in the body

which are difficult to access, in particular the deeper-situated parts of the respiratory system, as well as other internal organs, for example, liver and kidneys, which can be reached by means of a catheter either through the bloodstream or percutaneously. The length of the capsule connected axially to the cable is of essential importance, because the capsule must be manufactured from metal and is therefore rigid.

A radiation source of iridium-192 is generally used, because this isotope has very suitable radiation characteristics for therapeutic application. Further, U.S. patent 4,861,520 uses iridium-192 in the form of pellets. A capsule having eight iridium-192 pellets, as shown in figure 3 of this patent is used to achieve the desired radiation activity of approximately 10 Curie. The length of the reservoir provided within the capsule as shown in this figure 3 embodiment is approximately 4.5 mm; which contributes considerably to the total length of 6 mm for the rigid foremost portion of the device.

It is one object of the present invention to further reduce the length of the rigid foremost portion of the device.

According to the present invention, this object and others can be achieved by means of a device for introducing a radioactive source into the body for therapeutic application. The device according to the present invention comprises a flexible cable which can be introduced into the body through a catheter and a capsule connected coaxially to the front end of the cable, and sealingly accommodating a quantity of iridium-192 of a capacity sufficient for therapeutic application. The capsule comprises a thin-walled tubular reservoir, one end sealingly connected to

the flexible cable and a second end being closed and having a rounded-off external shape. The device according to the present invention is further characterized in that the capsule accommodates iridium-192 as the radiation source in the form of a single bar instead of a plurality of pellets as described in the prior art.

It has been discovered that by using a radiation source in the form of a single bar, that a considerable reduction of the length of the reservoir can be achieved, without substantial loss of radiation activity. For example, when the eight iridium pellets of the prior art are replaced by an iridium bar according to the present invention, the length of the reservoir is reduced by approximately 1 mm, but maintains an radiation activity of approximately 10 Curie. Consequently, the total length of the rigid foremost portion of the device may be reduced to approximately 5 mm. This reduction in reservoir length is achieved as a result of diminished play between the side wall of the reservoir and that of the bar, compared to that needed for the pellets. In loading the capsule with the radiation source, the pellets require sufficient play with regard to the inner wall of the reservoir to allow their accommodation therein, where as a bar may be introduced without substantial play. In addition, the pellets require a certain amount of mutual space between them after insertion into the reservoir, which space is eliminated when using a radiation source in the form of a bar. Also, a radiation source in the form of a bar may be accommodated in a narrow cavity more conveniently so that the manufacturing of the device according to the present invention is simplified.

The use of iridium-192 in the form of pellets as a source of radiation is common practice. Further, it is

generally known in the prior art, that during manufacture by irradiation of iridium-191 in a nuclear reactor, the iridium-191 is only converted at the outside of the targets, leaving the cores unconverted. This means, that the radiation sources obtained consist of a non-radioactive core surrounded by a layer of radioactive iridium-192. In addition, the eight iridium-192 pellets normally used to reach an radiation activity of approximately 10 Curie have a surface area that is approximately 100% grater than that of a single bar of iridium-192 having the same composite length. Therefore, it was expected that such a bar or iridium-192 would have a considerably reduced radiation activity, e.g. approximately 7.5 Curie. Consequently, in the prior art, iridium-192 in the form of pellets has apparently always been used as the radiation source. Surprisingly, however, it has now been discovered that the radiation activity of a bar of iridium-192 is substantially equal to that of a plurality of pellets with the same composite length.

In one embodiment according to the present invention, the device includes a reservoir having an open end and an integrally formed closed end, the open end being hermetically sealed by means of a plug which includes an elongated portion for insertion into the reservoir. Such a construction is described in U.S. patent 4,861,520. The back end of the flange of the plug is connected to the flexible cable by welding. In order to ensure a hermetic seal of the reservoir, the outer edge of the flange of the plug is circumferentially sealingly connected to the rear edge of the wall of the reservoir, also by welding. The plug disclosed in the above U.S. patent has a total length of approximately 1 mm, including the elongated portion which is inserted into the reservoir. In order to connect the plug to the flexible cable, the front end of the cable

must be rigidly fused or welded to enable the plug welding, thus adding to the overall length of the rigid portion of the device. It has now been discovered according to the present invention that the total length of the rigid portion of the device can be reduced by forming the plug as an integral part of the cable. In particular, if the plug is an integral part of the cable, a separate welded portion of the cable is no longer necessary to enable welding of the plug thereto, and the rigid portion of the device may be made approximately 0.5 mm shorter.

To avoid the risk that the radiation source may drop out of the reservoir after insertion, the walls of the reservoir are notched after introduction of the iridium-192 bar therein. This effectively locks the iridium-192 bar in place. Therefore, in a preferred embodiment according to the present invention, the inner wall of the reservoir includes a plurality of inwardly projecting bulges to keep the radiation source positioned within the reservoir. The bulges are formed at a slightly greater distance from the open end of the reservoir, than the length of the elongated portion of the plug.

In a another embodiment of the device according to the present invention, the capsule is formed integrally with the cable and constitutes a rigidly fused or melted forward portion. The capsule is provided with a bore for accommodating the radiation source, which bore is sealingly closed at its front end by welding, preferable by plasma welding. In this embodiment, the length of the rigid portion is considerably reduced, because neither a separate plug nor a plug integrally formed with the cable is required. Therefore, in this embodiment, the length of the rigid portion of the device may be a small as 0.5 to 1 mm greater than the inner length of the reservoir containing

the radiation source. To manufacture such a device, the foremost portion of the cable is fused or melted, after which a bore is drilled in the rigid portion for accommodating the iridium-192 radiation source. Following insertion of the radiation source, the open front end of the bore can be sealingly closed, preferably by using the technique of plasma welding.

In a further embodiment according to the present invention, a capsule having an open end and a closed end is used. The closed end of the capsule is welded to the front end of the capsule using any suitable technique, such as plasma welding. The open end of the capsule is sealed with a plug having an elongated portion for insertion into the open end of the reservoir. The plug also includes an extended portion which extends in a direction opposite from the elongated portion. The extended portion is connected to the main portion of the plug through an indented break away point. The extended portion of the plug enables a draw test to be conducted to check the strength and reliability of the weld between the capsule and cable. Once such a draw test has been satisfactorily completed, the extended portion of the plug may be broken off at the indented break away point.

Irradiation of enriched iridium-191 instead of normal iridium-191 in a nuclear reactor results in an approximately two time greater specific activity or iridium-192. Therefore, by using a radiation source produced by irradiation of enriched iridium-191, the volume of the reservoir for the radiation source can re considerably reduces, e.g. approximately by a factor of two. In this way, the length of the reservoir needed by a radiation activity of approximately 10 Curie can be reduced from approximately 4.5 mm to less than 2 mm. In other

words, more than a 2 mm reduction in the length of the rigid portion of the device can be achieved.

The invention will now be described in greater detail with reference to the drawing, in which;

Figure 1 is a longitudinal sectional view of a preferred embodiment of a device according to the invention,

Figure 2 shows on an exaggerated scale a part of the device shown in Figure 1, namely the part encircled at A, and

Figure 3 shows a longitudinal sectional vies of a further preferred embodiment of a device according to the invention.

The device shown for introducing a source of radioactive radiation into the body for therapeutic application comprises a flexible cable 10 having at its rear end a solid portion 11 for including information on the radiation source and at its front end a capsule 12. The flexible cable is twisted from a large number of strands of stainless steel. The cable has a diameter of approximately 1.1 mm and can be introduced into a patients's body through a catheter having an inside diameter of at least 1.3 mm. In this manner the deeper-situated organs can be reached by means of the radiation source accommodated in the capsule for the in situ treatment of tumors. The flexible cable may have any desired length depending on the place in the body which is to be reached and on the apparatus for positioning. The solid portion 11 is connected to the cable by welding.

The radioactive material 14 consisting of a single bar of iridium-192 with a capacity of radioactivity of approximately 10 Curie is enclosed in the capsule 12. The capsule consists of a thin-walled cylindrical reservoir of stainless steel having an externally rounded-off bottom 15 which is present at the front end of the device. The open end of the reservoir facing the flexible cable is sealed by means of a plug which is formed integrally with the cable by fusing or melting. The plug includes a first portion 16 having a reduced diameter extending within the cylindrical reservoir, which keeps the radioactive material enclosed within the reservoir and tightly fits within the wall 17 of the reservoir. A second portion 18 of the plug is formed integrally with first portion 16 and bears with its outer edge or flange on the rear edge of the wall 17 of the reservoir. As is clearly shown in Figure 2, the flange and the wall of the reservoir are circumferentially welded together by a weld 19, for example, by electron beam welding or laser welding, so that a reliable and hermetic seal of the reservoir is obtained. The plug is connected to the flexible cable, by another weld 20 at the prepared end 21 of the cable, also, for example, by laser welding or electron beam welding. As noted above, the plug is formed integrally with the cable, so that the first portion 16, extending within the reservoir, forms a part of the prepared end of the cable. Stringent requirements have to be imposed upon the outside dimensions of the rigid capsule 12 in order to reach the deeper-situated organs by passing through a catheter. A cylindrical reservoir having an external length of approximately 4.5 mm, measured from the front end of the bottom 15 to the rear edge of the flange of the second portion 18 of the plug, i.e. to the end of the prepared end of the cable, and having an outside diameter of approximately 1.1 mm is optimum because such dimensions provide sufficient space for a quantity of

radioactive material, in particular a single bar of iridium-192, with a radioactivity capacity of 10 Curie. Such a quantity of radioactivity is extremely suitable for the radiation treatment of tumors of internal organs, for example, lung tumors.

The wall 17, of the reservoir includes a plurality of notches 20, which appear as inwardly projecting bulges. The notches 20, act to keep the radiation source properly positioned within the reservoir, and help to avoid the risk of the iridium-192 bar dropping out of the reservoir.

Figure 3 shows a preferred embodiment of the present invention. In this embodiment a capsule 110, having an open end 112, and a closed end 114, is joined to flexible cable 100. In particular, the closed end 114, of capsule 110, is welded to cable 100, as indicated by weld 120. The capsule 110, includes a reservoir for containing a single bar 130, of iridium-192 which acts as a radiation source. The open end 112, of capsule 110, is hermetically sealed by means of a plug 140, which includes an elongated portion 142, for insertion into the open end 112, of capsule 110. The plug 140, further includes an extended portion 144, connected to the main body of the plug through an indented break point 146. The elongated portion 142, of plug 140, may be on approximately 0.5 mm in length, and still provide adequate sealing of the capsule 110. The extended portion 144, of plug 140, may be used as a grip portion during draw testing in order to assure the strength and reliability of weld 120. Following a successful draw test, the extended portion 144, may be broken off from the main body of plug 140, at break point 146. The device according to this embodiment is constructed in such a manner that the length of the rigid portion of the device may be from 0.5 to 1 mm greater than the length needed to accommodate the bar 130,

of iridium-192. In particular, the rigid portion of the device according to this embodiment is approximately 4.5 mm in length. If an enriched iridium-192 source is utilized, the length of the rigid portion of the device may be reduced even further.

What is claimed is:

1. A therapeutic device for introducing a source of radioactive radiation to a body comprising:
a flexible cable which can be introduced into the body through a catheter; and
a capsule for sealingly containing a source of radioactive radiation, the capsule comprising a thin-walled tubular reservoir having an open end which is sealingly connected to the flexible cable so that the capsule is coaxial to the flexible cable and having a closed end with a rounded-off external shape;
wherein said radioactive source is in the form of a single bar.

2. A device according to claim 1, wherein the open end of the reservoir is hermetically sealed to the flexible cable by means of a plug.

3. A device according to claim 2, wherein the plug is welded to the flexible cable.

4. A device according to claim 2, wherein the plug is formed integrally with the flexible cable.

5. A device according to claim 1, wherein the device is used to introduce radioactive radiation to internal organs.

6. A device according to claim 1, wherein the source of radioactive radiation has a radiation activity of about 10 Curie.

7. A device according to claim 1, wherein the reservoir

has as outside diameter no greater than about 1.1 mm and an external length including the sealing connection to the flexible cable of no more than about 4.5 mm.

8. A device according to claim 1, wherein the flexible cable is made of stainless steel.

9. A device according to claim 1, wherein the capsule is made of stainless steel.

10. A device according to claim 1, further comprising a plurality of inwardly projecting bulges formed on the interior wall of said reservoir, said bulges acting to retain said radioactive source within said reservoir.

11. A device according to claim 1, wherein said capsule is formed integrally with said cable and comprises a rigidly fused or melted portion of said cable, and wherein said capsule includes a bore for accommodating said radioactive source, said bore being sealingly closed at a front end by welding.

12. A device according to claim 11, wherein said bore is sealingly closed by plasma welding.

13. A device according to claim 1, wherein said radioactive source comprises a single bar of iridium-192.

14. A device according to claim 13, wherein said iridium-192 is formed by irradiation of enriched iridium-191.

15. A therapeutic device for introducing a source of radioactive radiation to a body comprising:
a flexible cable which can be introduced into the body through a catheter;
a capsule for sealingly containing a source of radioactive radiation, the capsule comprising a thin-walled tubular reservoir having a closed end which is sealingly connected to the flexible cable so that the capsule is coaxial to the flexible cable and having an open end; and
a plug for sealing said open end of said capsule;
wherein said radioactive source is in the form of a single bar.

16. A device according to claim 15, wherein said plug includes a main body portion; an elongated portion for insertion into said open end of said capsule; and an extended portion extending in a direction opposite of said elongated portion, and being connected to said main body portion through an indented break point.

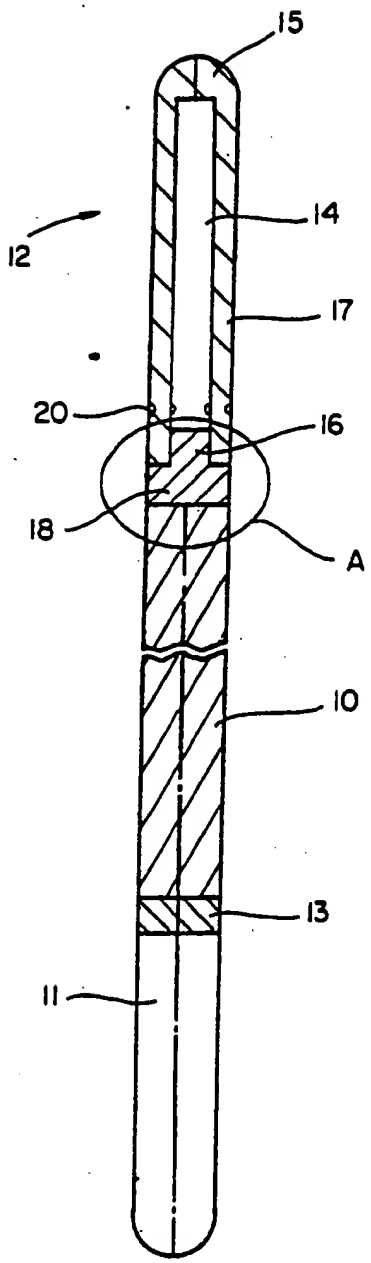

Fig. 1

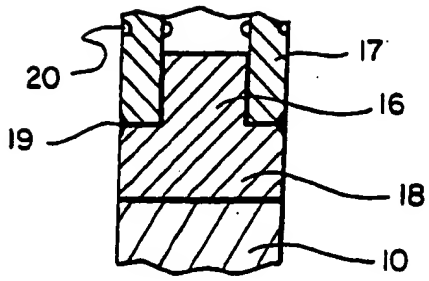

Fig. 2

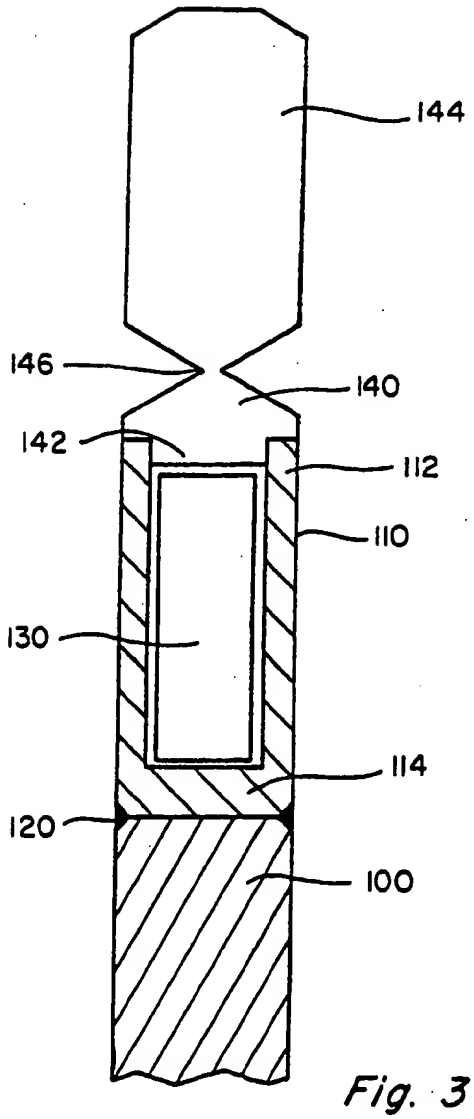

Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/US91/04934

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) A61M 36/12; A6IN 5/10
US 600/7

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	600/ 3, 6, 7

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	US, A, 4,819,618 (LIPRIE) 11 APRIL 1989 see entire document.	1-5,8,15 6,7,9, 11-14,16
Y	US, A, 4,861,520 (VAN'T HOOFT ET AL.) 29 AUSGUST 1989, see fig. 4	16
A	US, A, 3,750,653 (SIMON) 7 AUGUST 1973	1-16
A	US, A, 3,060,924 (RUSH) 30 OCTOBER 1962	1-16

* Special categories of cited documents: [15]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
18 OCTOBER 1991	07 NOV 1991
International Searching Authority [1]	**Signature of Authorized Officer** [20]
ISA/US	For KEVIN PONTIUS NGUYEN NGOC-HO INTERNATIONAL DIVISION

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